IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In Re Application of:	William J. Rea and Bertie B. Griffiths
Serial No.:	08/902,692
Attorney Docket:	16715CIP
Art Unit:	1644
Filed:	July 30, 1997
Examiner:	Schwadron, R.
For:	**Autogenous Lymphocytic Factor for Modification of T and B Lymphocyte Parameters**

APPELLANTS' REPLY BRIEF

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To: Assistant Commissioner of Patents
Washington, D.C. 20231

The Examiner's Answer in this case was sent electronically on May 8, 2012. This reply Brief is being filed pursuant to 37 CFR § 41.41.

A. The Examiner Originally Suggested "Chemically Sensitive"

The Examiner does not dispute that he originally suggested the term "chemically sensitive." The independent claims were amended nearly 13 years ago to be directed to a method for treating "a chemically sensitive individual," *which was originally suggested by the Examiner in a telephone conference on March 16, 1999, and which had been in the claims ever since*. See the Amendment filed April 17, 1999, page 4. (The claims as originally filed were directed to methods for regulating an "*abnormal lymphocytic cell cycle*" (claims 1–39) and for treating an individual "*having abnormal T and B lymphocyte parameters*" (claims 40–48)). For the first time in over 10 years, this language is used as the basis of a new rejection. This is after numerous

rejections on various other piecemeal grounds, all of which Applicants have overcome, including by making two different prior appeals to the Board of Patent Appeals and Interferences. The piecemeal examination of this application is contrary to the policy of the Patent and Trademark Office. MPEP § 707.07(g).

B. "Broadest-Construction" Standard

Appellants acknowledge that the PTO gives claims their "broadest reasonable interpretation" (Answer, pp. 12-13), but any such interpretation must be "*consistent with the* specification, ... and ... claim language should be read in light of the specification as it would be interpreted by one of ordinary skill in the art." *In re Bond*, 910 F.2d 831, 833, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990) (emphasis added). This standard does not relieve the PTO of its essential task of examining the entire patent disclosure to discern the meaning of claim words and phrases. *Rowe v. Dror*, 112 F.3d 473, 480, 42 USPQ2d 1550, 1555 (Fed. Cir. 1997). The protocol of giving claims their broadest reasonable interpretation is an examination expedient rather than a rule of claim construction. The broadest reasonable interpretation cannot be used as a justification for giving claims a legally incorrect meaning. *In re Skvorecz*, 580 F.3d 1262, 1267, 92 USPQ2d 1020, 1024-25 (Fed. Cir. 2009). "The broadest-construction rubric coupled with the term 'comprising' does not give the PTO an unfettered license to interpret claims to embrace anything remotely related to the claimed invention. Rather, claims should always be read in light of the specification and teachings in the underlying patent." *In re Suitco Surface, Inc.*, 603 F.3d 1255, 1260, 94 USPQ2d 1640, 1644 (Fed. Cir. 2010).

C. Irrelevant, Unfounded and Prejudicial Allegations; Extrinsic Evidence

In *Phillips v. AWH Corp.*, 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005) (en banc), the Federal Circuit emphasized that intrinsic evidence is of primary importance and that extrinsic evidence must be considered only in the context of the intrinsic evidence. *Phillips*, 415 F.3d at 1320-22, 75 USPQ2d at 1331. *See also OSRAM GmbH v. Int'l Trade Comm'n*, 505 F.3d 1351, 1356, 85 USPQ2d 1161, 1164 (Fed. Cir. 2007) ("The patent specification is the primary resource for determining how an invention would be understood by persons experienced in the field."); *Advanced Fiber Techs. (AFT) Trust v. J & L Fiber Services*, 674 F.3d 1365, 1374-75, 102 USPQ2d

1361, 1367 (Fed. Cir. 2012) (district court erred in relying on extrinsic evidence that contradicted the patent's specification, including the claims and written description). Here, the Examiner gave undue weight to "extrinsic evidence" at odds with the intrinsic evidence, and the specification and claims, in contravention to the findings in *Phillips* and subsequent Federal Circuit precedent.

The Examiner cites Orme (1994), Hall (2009), Barrett (2007) and Barrett (2005) (Answer, pp. 4-5). These articles are highly critical of "Multiple Chemical Sensitivity," "Environmental Medicine" and Dr. Rea generally but fail to address the claimed subject matter in the present application for patent. *See CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 1338, 68 USPQ2d 1940, 1944 (Fed. Cir. 2003) (the enablement analysis must be focused on the product or method defined by the claims). The only apparent purpose served by these documents is to impugn Dr. Rea's scientific credibility and character and they are not relevant to the patent application involved in the instant case.

Further, the Hall (2009), Barrett (2007) and Barrett (2005) references are dated long *after* the filing of the instant application for patent (July 30, 1997). The meaning of a claim is interpreted as of its effective filing date. *PC Connector Solutions, L.L.C. v. SmartDisk*, 406 F.3d 1359, 1363, 74 USPQ2d 1698, 1700 (Fed. Cir. 2005). *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1313, 75 USPQ2d 1321, 1326 (Fed. Cir. 2005) ("[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application."). *See also FS Networks Inc. v. A10 Networks, Inc.*, 2011 WL 3516054, at *3 (W.D. Wash. 2011) (articles published *after* the filing of the patents-in-suit were immaterial for purposes of evaluating the understanding of a person of ordinary skill in the art *at the time of filing*); *Pfizer Inc. v. Teva Pharms. USA, Inc.*, 803 F.Supp.2d 397, 404 n.11 (E.D. Va. 2011) (FDA approval and associated documents had no relevance in claim construction because they were not in existence at the time of the patent filing).

Barrett (2007) references a complaint filed against Dr. Rea with the Texas Medical Board in 2007 (10 years *after* the filing date). The Examiner persists in relying on the bare fact of this complaint (Answer, pp. 5-6) even though it's undisputed that the complaint was resolved by Mediated Agreed Order (a settlement agreement) on August 27, 2010 without adjudication or findings. Rea Decl. ¶¶ 14 & 18, Ex. A, pp. 30-31; *Kloeris v. Stockdale*, 2010 WL 141305, at *9

(Tex.App.—Houston [1st Dist.] 2010, pet. denied). The matter concerned different treatment methods (use of chemical antigens, oxygen treatments, etc.) not at issue in the present application for patent or the claims. See the Agreed Order, at p. 3, ¶ 3; Rea Decl. ¶ 16, Ex. A, p. 31. To settle that matter, Dr. Rea agreed to change the Informed Consent documents used in his medical practice. Rea Decl. ¶¶ 12-20, Ex. A, pp. 30-31.

Hall (2009) references a television "profile" on "Nightline" in 2008 (interview with Dr. Rea and subsequent "rebuttal") and a "recent example of [Dr. Rea's] published scientific studies." (Answer, p. 15). Hall (2009) does not address the claimed subject matter in the present application for patent. See Rea Decl. ¶ 23. Further, the writings and speeches of an inventor named in a patent that are not incorporated into a patent's specification or prosecution history may not be used to limit the patent's scope. 5A *Chisum on Patents* § 18.03[2][e][iii] (2012). *See North Am. Vaccine, Inc. v. American Cyanamid Co.*, 7 F.3d 1571, 1578, 28 USPQ2d 1333, 1338 (Fed. Cir. 1993) (rejecting the district court's reliance on the inventor's speeches and writings; "A patent is to be interpreted by what it states rather than by what the inventor wrote in a scientific publication.").

D. The Examiner Misinterprets the Specification

The specification never asserts that chemical sensitivity "causes" or "is linked to" a "plethora of disease" as the Examiner claims. (Answer, pp. 6, 14). The Examiner is apparently relying on extrinsic evidence to infer this proposition which does not appear in the specification.

Contrary to the Examiner's implication, the specification states (at page 4, lines 6–20) (*emphasis added*):

> [T]he application of this invention is useful in the study of the immune system, and … is not limited to the treatment of a certain category of individuals. For example, the method can be applied to the study and/or clinical treatment of individuals suffering from a ***suppressed, dysfunctional***, or deregulated ***immune system for any number of possible causes***. However, the emphasis of this invention is on the treatment of the individuals who have ***compromised immune systems*** that result in an ***abnormal susceptibility to environmental chemicals (chemically sensitive)***…

Contrary to the Examiner's new interpretation, "chemical sensitivity" or "chemically sensitive individual" refers to symptoms, not to syndromes or diseases. 9/20/2010 Declaration of William J. Rea, ¶¶ 27–31, Ex. A, pp. 32-33. The specification defines and uses "chemically sensitive" referring to symptoms. 9/20/2010 Declaration of William J. Rea, ¶¶ 32–35, Ex. A, p. 34.

The specification (at page 4, lines 10–14) defines how the term "chemically sensitive" is being used in the specification and claims (*emphasis added*):

> ... However, the emphasis of this invention is on the treatment of the individuals who have compromised immune systems *that result in an abnormal susceptibility to environmental chemicals (chemically sensitive)*, pollens, dust, molds, food (allergies), bacteria and non-HIV viruses with recurrent infections.

In addition, the specification (at page 13, lines 16–19) identifies this principal characteristic of "chemically sensitive individuals":

> The total of 290 chemically sensitive individuals that were investigated in these studies were affected principally by environmental incitants found in categories such as food, biological inhalants, and chemicals. They presented histories of varied backgrounds, but common among them was that all showed irregular cell cycles including T and B lymphocytes ...

The term "chemically sensitive" individual is defined and used in the specification and claims with reference to *symptoms, signs and abnormal laboratory data*.

The application does *not* use the term "multiple chemical sensitivity." The claims are *not* directed to "multiple chemical sensitivity" (aka "MCS"). 9/20/2010 Declaration of William J. Rea, ¶ 36, Ex. A, p. 34. "Multiple chemical sensitivity" ("MCS") refers to a syndrome. 9/20/2010 Declaration of William J. Rea, ¶¶ 37–40, Ex. A, p. 35. "Chemical sensitivity" symptoms are *not* "multiple chemical sensitivity" syndrome and should not be equated. 9/20/2010 Declaration of William J. Rea, ¶ 41, Ex. A, pp. 35-36. The claims are *not* directed to other diseases. 9/20/2010 Declaration of William J. Rea, ¶¶ 33–34, Ex. A, p. 34.

The Examiner's interpretation is contrary to the specification and the record as a whole. *See In re Sichert*, 566 F.2d 1154, 1160–61, 196 USPQ 209, 214 (CCPA 1977) (in patent application for therapeutical compositions for treating lymphatic congestions, rejection for lack of enablement was improper, since ***there was no need for a disclosure*** as to which diseases are encompassed by the term "lymphatic congestions" ***when the meaning of that term*** was limited to simple lymphatic congestion (clogged lymph vessels) and did not extend to the causes or results of lymphatic congestion (various therapy resistant diseases); "The record clearly shows that the compositions were developed for the 'activation and regeneration of the lymphatic vessels …; that one of the ***criteria for determining the effectiveness*** of the composition is the 'tendency of the swellings of the tissues to decrease …; that these compounds are 'suited to diminish inflammatory changes in the lymphatic system …; and that the result of treatment is 'the effective drainage of the entire lymphatic system.").

Here, the specification describes the efficacy of the claimed method in terms of its effect on symptoms.

For example, the specification states (at page 11, line 22 – page 12, line 3):

> Initial clinical testing indicates that a first treatment … can have a significant effect on improving the individual's T and B lymphocyte parameters. The regulatory effect can be objectively measured … by determining the individual's lymphocytic cell cycle … and also measured by cell mediated immunity by skin tests as well as symptoms and signs scores.

The specification also states (at page 14, lines 1–7):

> Significant changes were observed in patients treated with ALF. Changes were observed in improvement of overall clinical manifestations and immune studies. … [T]here were significant regulations of lymphocytic cell cycles … Patients became less sensitive to exposures and more tolerant to specific incitants.

The specification states (at page 16, lines 19–22):

> The severity of hypersensitive reaction, fatigue, recurrent infections, depression, concentration seemed to improve significantly. … The frequencies of hypersensitive reaction, recurrent infections, fatigue, headaches, and depression were also altered.

The specification explains that: "[T]he hypersensitivity reactions markedly decreased or disappeared. … [R]ecurrent infection, fatigue, headaches, depression, concentration, even gastrointestinal upsets were also improved." *Id.* at page 18, lines 21–24.

The specification states: "Symptoms and signs scores are seen in TABLE 15 and TABLE 16. Significant improvement occurred … The severity of hypersensitive reaction, fatigue, recurrent infections, depression, concentration seemed to improve significantly. The frequencies of hypersensitive reaction, recurrent infections, fatigue, headaches, and depression were also altered." *Id.* at page 20, lines 16–20. The specification also states: "TABLE 22 shows a case study of one … HIV-positive patient … After restarting the ALF treatment, all her clinical symptoms disappeared again." *Id.* at page 22, lines 6–12.

Pending claims 49–64 and 67 are directed to "A method for treating a chemically sensitive individual having an irregular cell cycle for T lymphocytes …." Claim 70 is similar to pending Claim 49 *except* that the preamble does *not* include the language "having an irregular cell cycle for T lymphocytes."

In addition, the specification and claims do not require the irregular cell cycle for T lymphocytes be "*normalized*." Of course, this is a desired goal, but the claims are directed to "*treating,*" which is illuminated by the specification:

> … treating the individual with a therapeutic amount of the ALF, and determining the individual's lymphocytic cell cycle to observe any regulatory effect on the lymphocytic cell cycle and subsets.

Specification, page 6, lines 16–18.

> … As treatment [with ALF] continued, in general, in about six weeks a more drastic shift *toward that of a normal profile was observed.*

Specification, page 14, lines 8–9 (*emphasis added*).

It is for the invention ***as claimed*** that enablement must exist. The term "normalizing" does not appear in the claims. The claims state no standard of regulation. The application and claims do not require complete regulation, but is *a basis* for regulation of the cell cycle.

9/20/2010 Declaration of William J. Rea, ¶¶ 47–49, Ex. A, pp. 37-38. *See CFMT Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 1338, 68 USPQ2d 1940, 1944 (Fed. Cir. 2003) (patents for semiconductor wafer cleaning system were not invalid for lack of enablement, even if embodiment did not, without significant additional modifications, succeed in meeting user's cleanliness requirements; patents did not claim particular standard of cleanliness); *In re Cortright*, 165 F.3d 1353, 1359, 49 USPQ2d 1464, 1468 (Fed. Cir. 1999) (claims to method of "restoring hair growth" encompassed achieving full head of hair but did not require it).

E. Appellants Demonstrated Enablement for the Claimed Invention; Evidence of Treating an Irregular Cell Cycle for T Lymphocytes

The Examiner complains that the data in Figures 2–4 "provides no information about the cell cycle of human peripheral B lymphocytes from 'normal' volunteers." (Answer, p. 8). But the normal cell cycle for both T and B lymphocytes was well known at the time the invention was made and the application was filed. 9/20/2010 Declaration of William J. Rea, ¶¶ 50–56, Ex. A, pp. 38-39. The specification evidences improvement in the cell cycle for T lymphocytes. 9/20/2010 Declaration of William J. Rea, ¶¶ 57–67, Ex. A, pp. 39-42. In the Answer, on page 8, the Examiner continues: "Figures 3a–3c purport to show the 'irregular cell cycle profiles from environmentally compromised individuals.' There is no disclosure as to what cells are referred to in said figure …" However, it is clear from the specification that unless otherwise specified, the "cell cycle" refers to the cell cycle for mixed T and B lymphocytes, including all subsets, which is disclosed to present a reflection of the status of the T lymphocytes, including all subsets. No other interpretation is reasonable. 9/20/2010 Declaration of William J. Rea, ¶ 61, Ex. A, p. 40.

Among other evidence provided in the specification, the written description states:

> Significant changes *were typically observed in patients treated with ALF*. Changes were observed in improvement of overall clinical manifestations and immune studies. With regard to clinical manifestations, minimal symptoms (which were improved over the onset symptoms) continued after three weeks of continued therapy with ALF. *Immunologically, there were significant regulations of cell cycles, especially from one phase of the cycle to another, and changes in T and B lymphocyte numbers and functions*. Patients became less sensitive to exposures and more tolerant to specific incitants. As treatment continued,

> *in general*, in about six weeks a more drastic shift *toward that of a normal profile* was observed.

Specification, page 14, lines 1–8 (*emphasis added*).

The Examiner also states (p. 8) that "it appears that the cell cycle of untreated patients in Figure 4a more closely approximates that seen in the normal controls …." Figures 4a–c represent *a single case history*. These figures *illustrate* to a person of skill in the art a drastic improvement in the cell cycle, which is a reflection of the improvement of the cell cycle for T lymphocytes. 9/20/2010 Declaration of William J. Rea, ¶ 67, Ex. A, pp. 41-42.

In addition, the claims do not require regulation of the cell cycle in patients suffering from autoimmune disease. 9/20/2010 Declaration of William J. Rea, ¶¶ 68–70, Ex. A, p. 42.

The results obtained are too large to attribute to the placebo effect or any of the other therapies or treatments that had been used until that time in environmental medicine. 9/20/2010 Declaration of William J. Rea, ¶¶ 71–72, Ex. A, pp. 42-43. In addition, a theoretical explanation was offered in the specification. 9/20/2010 Declaration of William J. Rea, ¶¶ 73–74, Ex. A, p. 43.

Claim 70 is argued separately only to point out there is even less justification for reading a "normalizing" standard into Claim 70 (subhead I, *supra*).

Claim 70 is similar to pending Claim 49 except that the preamble does not include the language "having an irregular cell cycle for T lymphocytes."

Regarding Claims 49–64 and 67, the specification provides evidence of enablement for use in treating certain individuals: those who are chemically sensitive and have an irregular cell cycle for T lymphocytes. Regarding Claim 70, the specification provides evidence of enablement for use in treating those who are chemically sensitive.

As discussed (above subhead I), "treating," properly construed, does not mean "normalizing" the irregular cell cycle for T lymphocytes. This interpretation is even more compelling regarding Claim 70, which does not recite "having an irregular cell cycle for T lymphocytes."

F. The Examiner Failed to Consider Appellants' Evidence

Applicants submitted the September 20, 2010 Declaration of Dr. William J. Rea, Ex. A, in response to the 3/18/2010 non-final Office action. However, the Examiner has essentially ignored Applicants' evidence and failed to specifically explain why the evidence is insufficient.

Applicant's evidence ***must*** be considered. A declaration or affidavit is, itself, evidence that ***must*** be considered. MPEP § 2164.05. The examiner must then weigh all the evidence before him or her, including the specification and any new evidence supplied by applicant and decide whether the claimed invention is enabled. *Id.* *See* MPEP § 716.01: "Evidence traversing rejections must be considered by the examiner whenever present. … Where the evidence is insufficient to overcome the rejection, the examiner must specifically explain why the evidence is insufficient." *See also In re Alton*, 76 F.3d 1168, 1174, 37 USPQ2d 1578, 1583 (Fed. Cir. 1996) (declarations relating to the written description requirement should have been considered).

G. Conclusion

Based on the foregoing evidence, arguments, and authorities, it is respectfully requested that the rejection of pending Claims 49–64, 67 and 70 under 35 U.S.C. § 112, first paragraph, be reversed and the application be allowed for issue.

Dated: June 26, 2012.

Respectfully submitted,

/s/ Todd E. Albanesi

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